

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 14-14450

SCOTTY'S INC., et al.,

Defendants.

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Now before the court is Plaintiff United State's Motion for Summary Judgment (Dkt. # 22), seeking injunctive relief pursuant to 21 U.S.C. § 332 for violations of the federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. §§ 331(a) and (k). The matter is fully briefed, and the court finds that a hearing is unnecessary. See E.D. LR 7.1(f)(2). For the reasons stated below, the court will grant the government's Motion.

I. BACKGROUND

For fifty-five years, the Bruce family has owned and operated Defendant Scotty's, Inc., a small, Detroit-based company that manufactures, sells, and distributes ready-to-eat sandwiches to gas stations and convenience stores located throughout Michigan and Ohio. (Dkt. # 22, Pg. ID 588; Dkt. # 26, Pg. ID 641, 653.) On five separate occasions over the last decade, the Food and Drug Administration ("FDA") inspected Defendants' headquarters located at 3426 Junction Street: first in August 2006, then subsequently in August 2008, August 2009, October 2010, and January-February 2014. (Dkt. # 22, Pg. ID 590-605.) On each of these occasions, inspectors discovered

multiple violations of the Seafood Hazard Analysis and Critical Control Point (“HACCP”), 21 C.F.R § 123.6, and Current Good Manufacturing Practice (“CGMP”), *Id.* at § 110.5, regulations. (*Id.*) The HACCP regulations govern all establishments that “process fish and fishery products” and apply to Defendants because they manufacture and sell tuna salad sandwiches. *Id.* at § 123.6. Similarly, the CGMP is applicable to all food processors, except those harvesting, storing, or distributing raw agricultural commodities. *Id.* at § 110.19.

Among others, Defendant Scotty’s was cited for the following violations:

(1) failing “to have a written HACCP plan to control the food safety hazards reasonably likely to occur during the processing of tuna salad sandwiches,” (Dkt. # 22, Pg. ID 590; Dkt. # 26, Pg. ID 643); (2) storing tuna salad sandwiches in reduced oxygen packages, (*Id.*); (3) failing to maintain the requisite sanitation control record, (*Id.* at Pg. ID 591; Dkt. # 26, Pg. ID 643); (4) maintaining the plant in state of disrepair, as evidenced by the moldy ceiling tiles in the walk-in cooler where Defendants store sandwiches, (Dkt. # 22, Pg. ID 592; Dkt. # 26, Pg. ID 643); (5) failing to “properly identify toxic cleaning compounds and sanitizing agents in a manner that protects against contamination of food,” (Dkt. # 22, Pg. ID 593; Dkt # 26, Pg. ID 644); (6) allowing personnel to process food with bare hands without removing jewelry, (Dkt. # 22, Pg. ID 593); (7) lacking “adequate hand-washing facilities,” (*Id.* at Pg. ID 594); (8) storing production materials such as bread buns in plastic trays and plastic wrap directly on the floor, (Dkt. # 19-5, Pg. ID 398-99); and (9) failing to “remove litter and waste that serves as an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant building,” (*Id.* at Pg. ID 595).

After each inspection, FDA investigators issued Forms FDA 483 to Defendant Sandra J. Jackson, Scotty's co-owner and manager, and discussed each of the observed violations with her. (*Id.* at Pg. ID 605.) Each time, Jackson "promised to make the necessary corrections." (*Id.*) Additionally, at the conclusion of the 2008, 2009, 2010, and 2014 inspections, "Defendant Jackson promised that Defendants would stop processing tuna salad sandwiches, so as to avoid the obligation to comply with the seafood HACCP regulations." (Dkt. # 22, Pg. ID 605; Dkt. # 26, Pg. ID 651). Nevertheless, few of the promised improvements were made year-to-year between inspections, and Defendants continue to make tuna salad sandwiches. (Dkt. # 22, Pg. ID 605-06; Dkt. # 26, Pg. ID 651.)

In addition, the FDA has sent Defendants three follow-up letters. First, in a December 5, 2006 letter, agency officials "detail[ed] Defendants seafood HACCP violations[,] . . . discuss[ing] in detail what the seafood HACCP regulations require and referr[ing] Defendants to additional resources on the FDA's website." (Dkt. # 22, Pg. ID 607; Dkt. # 26, Pg. ID 653.) Defendants did not respond. (*Id.*) Then, on November 19, 2009, the FDA sent Defendants a warning letter which elaborated on many of the regulatory violations and reminded Jackson "that she told FDA investigators during the August 2009 inspection that she would stop processing tuna salad sandwiches as of August 27, 2009." (Dkt. # 22, pg. ID 606.) Jackson responded in kind with a letter ten days later, "promising corrective actions," but suggesting "that she was continuing to process tuna salad sandwiches." (*Id.*), The agency responded with a follow-up letter two months later, stating that "Defendants' response was inadequate because Defendants failed to address the issues in the Warning Letter in sufficient detail." (Dkt.

22, Pg. ID 607.). Defendants, once again, did not respond. (Dkt. # 22, Pg. ID 607; Dkt. # 26, Pg. ID 653.)

After Defendants failed their fifth inspection in 2014, Plaintiff United States commenced the present action for injunctive relief pursuant to 21 U.S.C. § 332.

II. STANDARD

Summary judgment is proper “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “In deciding a motion for summary judgment, the court must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party’s favor.” *Sagan v. United States*, 342 F.3d 493, 497 (6th Cir. 2003). The movant has the initial burden of showing the absence of a genuine dispute as to a material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). “[T]hat burden may be discharged by showing . . . that there is an absence of evidence to support the nonmoving party’s case.” *Bennett v. City of Eastpointe*, 410 F.3d 810, 817 (6th Cir. 2005) (internal quotation marks omitted).

The burden then shifts to the nonmovant, who must put forth enough evidence to show that there exists “a genuine issue for trial.” *Horton v. Potter*, 369 F.3d 906, 909 (6th Cir. 2004) (citation omitted). Summary judgment is not appropriate when “the evidence presents a sufficient disagreement to require submission to a jury.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 243 (1986). In evaluating a summary judgment motion, “the judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial . . .

credibility judgments and weighing of the evidence are prohibited.” *Moran v. Al Basit LLC*, 788 F.3d 201, 204 (6th Cir. 2015) (internal quotation marks and citations omitted).

III. DISCUSSION

The government now seeks injunctive relief under section 332(a) of the Federal Food, Drug, and Cosmetic Act, which authorizes district courts “to restrain violations of section 331” of the Act “for cause shown.” 21 U.S.C. § 332(a). When, as here, “a court is called upon to enforce a federal statutory injunction, its reliance upon the traditional practices of equity must be ‘conditioned by the necessities of the public interest which Congress has sought to protect.’” *United States v. City of Painesville*, 644 F.2d 1186, 1194 (6th Cir. 1981). Therefore, unlike with a standard injunction determination, courts do “not need to consider whether there is an adequate legal remedy or irreparable injury.” *United States v. S. Serra Cheese*, No. 14-13077, 2015 WL 6156961, at *6 (E.D. Mich. Oct. 20, 2015) (Cohn, J.). Instead, “the Government only needs to establish that [Defendants] violated the statute and there is some cognizable danger of recurrent violation.” *Id.*; see also *United States v. Edward Rose & Sons*, 246 F. Supp. 2d 744, 753 (E.D. Mich. 2003) (“[P]laintiff need only show that there has been a violation of the SEC and that future violations are reasonably likely to occur.”). Each factor will be discussed in turn.

A. Violation of the Act

The government argues that Defendants have violated the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a) and (k). The court agrees. Section 331(a) of the Act prohibits the “introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated or misbranded.” 21 U.S.C. § 331(a). Subsection (k)

similarly restricts “doing any other act with respect to, a food . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated.” *Id.* at § 331(k). Thus, to prove the alleged violations, the government must show that (1) Defendants’ products constitute “food” within the meaning of the legislation; (2) Defendants either introduced said food into interstate commerce, 21 U.S.C. § 331(a), or held it for sale after shipment in interstate commerce, 21 U.S.C. § 331(k); and (3) said food is adulterated. *S. Serra Cheese Company*, 2015 WL 6156961, at *4.

The government claims that “[n]o genuine issue as to any material fact exists in this case.” (Dkt. # 22, Pg. ID 618). Indeed, Defendants have not attempted to argue prongs one and two, admitting that their sandwiches are “food” within the meaning of the Act and that they have introduced those sandwiches into interstate commerce. (Dkt. # 26, Pg. ID 641.) Instead, Defendants rely on the unexplained assertion that “[t]here are genuine issues of fact as to *some* of the alleged violations.” (Dkt. # 26, Pg. ID 656 (emphasis added).) Rather than providing evidence to support this claim, however, Defendants rely on the non-sequitur that “the company has never received a complaint of having sold an un-wholesome sandwich.” (*Id.* at Pg. ID 654.)

Food is adulterated within the meaning of the Act “if it has been prepared, packed, or held under insanitary conditions whereby it may have be contaminated with filth, or whereby it may have been rendered injurious to health.” 21 U.S.C. § 342(a)(4). “This provision of the Act pertains solely to the conditions under which food is prepared, packaged, or held; it is not necessary to prove that the food itself actually contains filth or is injurious to health.” *S. Serra Cheese*, 2015 WL 6156961, at *4. On the contrary,

“the government need only show a reasonable probability that, because of the insanitary conditions under which food is prepared, packed, or held, food may have been rendered filthy or injurious to health.” *Id.* (citing *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 90-91 (1964); *Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952); *United States v. Gel Spice Co., Inc.*, 601 F. Supp. 1205, 1211 (E.D.N.Y. 1984)). “The question of insanitary conditions is to be determined from the totality of the circumstances.” *United States v. Am. Mercantile Corp.*, 889 F. Supp. 2d 1058, 1075-76 (W.D. Tenn. 2012).

1. The HACCP Violations

Federal regulations interpreting this Act require “every processor” of “fish or fishery products” to “conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by the processor and to identify the preventative measures that the processor can apply to control those hazards.” 21 C.F.R. § 123.6(a). Whenever said “hazard analysis reveals one or more food safety hazards that are likely to occur,” a processor is required to “have and implement a written HACCP plan” detailing

- (1) the safety hazards which are likely to occur;
- (2) the “critical control points for each of the identified food safety hazards;”
- (3) “the critical limits that must be met at each of the critical control points;”
- (4) a list of procedures that “will be used to monitor each of the critical control points to ensure compliance;”
- (5) any corrective action plans developed by the processor to correct deviations;
- (6) the processor’s verification procedures; and

(7) a “recordkeeping system that documents the monitoring of the critical control points.”

Id. at § 123.6(b). “Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary . . . shall render the fish or fishery products of that processor adulterated” as a matter of law. *Id.* at § 123.6(g).

The government argues that Defendants’ tuna salad sandwiches are adulterated within the meaning of the Act because “Defendants have repeatedly failed to establish and implement a HACCP plan that addresses food safety hazards that are likely to occur when processing tuna salad sandwiches,” including “the formation of scombrototoxin, the growth of pathogens and the formation of additional toxins, and the presence of allergens.” (Dkt. # 22, Pg. ID 591, 624.) Defendants do not dispute that the manufacture and distribution of their tuna salad sandwiches pose significant health risks to the public, and “admit that at the time alleged they did not have a written HACCP plan in place.” (Dkt. # 26, Pg. ID 643.) Nevertheless, they argue that “based on advice received from FDA inspector Rasha Bamieh in 2008, they believe[d] Scotty’s production of a limited amount of tuna sandwiches, pursuant to a special order, and both produced and delivered to a customer within 6 hours, exempted Scotty’s from *any* required compliance with the HACCP regulations.” (*Id.* at Pg. ID 642 (emphasis added).) No such exemption exists within the regulations or the Act. Even if it did, the government has provided evidence that shows “tuna salad sandwiches produced by Defendants for customers . . . were stored in the firm’s walk-in cooler . . . until being stored in the firm’s delivery trucks overnight.” (Dkt. # 29, Pg. ID 677; *see also* Dkt. # 20-2, Pg. ID 434.) Defendants have proffered nothing to rebut this evidence. As such, the tuna salad

sandwiches in question were not “produced and delivered to a customer within 6 hours.” Defendants’ operation is not exempted from the HACCP regulations.

Defendants are essentially arguing good faith, but as the Ninth Circuit has noted “if it is shown that the product proceeded against is adulterated or misbranded, then good faith or lawful intent will not constitute a defense.” *Research Labs., Inc. v. United States*, 167 F.2d 410, 420 (9th Cir. 1948); *see also* 13 Fed. Proc., L. Ed. § 35:500 (“Violations [of the Food, Drug, and Cosmetic Act] may be punished as misdemeanors regardless of a lack of knowledge, willfulness, or personal participation by the defendnat.”). Having admitted that they did not have an HACCP plan in place, Defendants must also admit that the tuna salad sandwiches are adulterated as a matter of law.

2. CGMP Regulations

Violations of CGMP regulations are also independently indicative of a food being adulterated within the meaning of the Act. 21 C.F.R. § 110.5(a). These regulations require the “grounds about a food plant under the control of the operator [to be] kept in a condition that will protect against the contamination of food.” *Id.* at § 110.20(a). It also mandates that “plant management shall take all reasonable measures and precaution to ensure” disease control, cleanliness, and the education, training, and supervision of personnel with respect to proper sanitation when handling food products. *Id.* at § 110.10. Among other things, the regulations require employees to wash their “hands thoroughly . . . in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated,” *Id.* at § 110.10(3); “remov[e] hand jewelry that cannot

be adequately sanitized during periods in which food is manipulated by hands,” *Id.* at § 110.10(4); and “tak[e] any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances,” *Id.* at § 110.10(9).

The government has shown that during their inspections of Defendants’ facilities, FDA agents documented multiple CGMP violations including: (1) mold-covered ceiling tiles in the walk-in cooler where Defendants stored sandwiches (Dkt. # 19-5, Pg. ID 399); (2) employees touching non-food contact surfaces, including plastic bakery racks stored outside near the trash, before handling food products without washing their hands, (*Id.*); (3) an employee handling food without first removing a large gemstone ring, (*Id.* at Pg. ID 400); (4) “[p]lastic wrap used to wrap various [ready-to-eat] sandwiches . . . stored directly on the floor in front of a processing table during the manufacturing of . . . sandwiches,” (*Id.* at Pg. ID 398); (5) plastic bakery racks holding bread buns stored directly on the floor and in the ally near the trash which were later placed directly on the production table without first being sanitized, (*Id.* at Pg. ID 398, 399); (6) a “[l]ack of effective hand cleaning preparations,” specifically noting a “hand wash sink located in the meat slicing/dishwashing room” that did “not have readily available hand soap,” (*Id.* at Pg. ID 400); and (7) a “[f]ailure to remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings,” (*Id.*).

Defendants even admit that some of these violations occurred, including the moldy ceiling tiles and employees placing the bread bun racks directly on the floor, but insist that following the inspection, “they promptly took steps to prevent a reoccurrence

of any errors of such nature as were reported by the inspector,” and “arranged to have the missing or discolored ceiling tiles replaced.” (Dkt. # 26, Pg. ID 644.) To support these assertions, Defendants have provided the court with only two bare-bone affidavits, one by Defendant Jackson and the other by her father, David Bruce. For her part, Jackson claims that “[e]xtensive physical improvements have been made to our food production facility, and these improvements are continuing.” (Dkt. # 26-3, Pg. ID 662.) Similarly, Bruce states that “[i]mprovements in Scotty’s, Incorporated’s physical facilities and its sandwich-making practices have taken place during this litigation, and it expects to finish the planned improvements by the end of November, 2015, if given the opportunity to do so.” (Dkt. # 26-5, Pg. ID 666.) Neither affidavit refute any of the specific violations shown by the government. To the extent these affidavits address such violations, they discuss only *future* corrective plans, and are thus insufficient to create a genuine issue for trial. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (a non-movant “must do more than simply show that there is some metaphysical doubt as to material facts . . . [and] come forward with specific facts showing that there is a genuine issue for trial”).

Defendants have provided even less evidence to support its denials of the government’s other allegations, including employees not washing their hands before handling Defendants’ products after touching non-food contact surfaces, an employee handling food without first removing hand jewelry, the lack of soap at the hand washing station, and the failure to remove trash. In each case, Defendants either deny the allegations out right, (See, e.g. Dkt. # 26, Pg. ID 644), or state that if such violations occurred, they were in contradistinction to Defendants’ “standard rules.” (*Id.*) The only

piece of evidence Defendants cite to support any of these denials is paragraph fourteen of Defendant Jackson's affidavit, which states "I have read the plaintiff's motion for summary judgment and the response by Scotty's and myself. The facts stated therein are true and correct to the best of my knowledge, information and belief." (Dkt. # 26-3, Pg. ID 662.) This sort of circular reasoning is certainly not "more than a scintilla" of evidence. *S. Serra Cheese*, 2015 WL 6156961, at *5 (stating that argument fails because "aside from the assertions in its brief, Serra has not established proof of the assertions"). As such, Defendants have not raised a genuine issue of material fact with respect to its CGMP violations. In light of these violations, the court finds that there is a "reasonable probability that, because of the insanitary conditions under which [Defendants' sandwiches are] prepared, packed, or held, [they] may have been rendered filthy or injurious to health." *S. Serra Cheese*, 2015 WL 6156961, at *4. Defendants' sandwiches are adulterated as a matter of law.

B. Likelihood of Future Violations

Having already determined that Defendants violated the Act, the court turns to the second factor: the likelihood of Defendants violating the Act in the future. When making this determination, courts consider a number of factors, including:

- (1) the egregiousness of the violations;
- (2) the isolated or repeated nature of the violations;
- (3) the degree of scienter involved; and
- (4) the sincerity of the defendant's assurances, if any, against future violations.

Edward Rose & Sons, 246 F. Supp. 2d at 753-53. While this is not an exhaustive list and no single factor is dispositive, *Id.*, all of the relevant factors suggest that an injunction is warranted to prevent future violations of the Act.

First, as noted above, Defendants' past violations were particularly egregious, present in nearly every aspect of their sandwich-making operation. This factor weighs in favor of granting injunctive relief.

Second, many of Defendants' regulatory violations date back to at least August 2006, when the FDA inspectors first noted Scotty's lack of a written HACCP plan, failure to maintain sanitation control records, and practice of placing bread buns in plastic trays directly on the floor. (Dkt. # 22, Pg. ID 604; Dkt. # 26, Pg. ID 651.) Despite Defendants' unsubstantiated claims to the contrary, Defendants did not take the "necessary action to correct [these] conditions." (Dkt. # 26, Pg. ID 651.) These and other violations of the HACCP and CGMP regulations continued, and were documented in each of the FDA's four subsequent inspections. (Dkt. ## 20-3, 20-5, 20-6, 20-7, 20-8, 20-9.) As the Sixth Circuit has noted, such a "pattern of repetitive violations . . . weigh[s] heavily in favor of granting a prospective injunction." *Martin v. Funtime, Inc.*, 963 F.2d 110, 114 (6th Cir. 1992).

Third, in light of the FDA's repeated warnings, (Dkt. ## 20-3, 20-4, 20-5, 20-6, 20-7, 20-8, 20-9, 20-10, 21, 21-2), there is no question that Defendants have knowingly violated the Act since August 2006. Thus, this factor cuts in favor of the government as well.

Fourth, Defendants admit that after each inspection, Defendant Jackson "promised corrections to many of the CGMP violations," (Dkt. # 22, Pg. ID 595, 601, 603, 605; Dkt. # 26, Pg ID 646, 648, 649, 650, 651). Yet, the violations persisted. Furthermore, Defendants admit that following the 2008, 2009, and 2010 inspections, Defendant Jackson also promised "that Defendants would stop processing tuna salad

sandwiches.” (Dkt. # 22, Pg. ID 605; Dkt. # 26, Pg. ID 649, 650, 652.) Yet, production continued. Given the emptiness of their past promises, Defendants’ present contrition and promises of reform are dubious at best.

Nevertheless, Defendants essentially argue that this time around they really mean it, as evidenced by the fact that Scotty’s “has made a substantial financial commitment by obtaining well-trained and competent advisors from Wayne State University to assist it in meeting FDA’s requirements.” (Dkt. # 26, Pg. ID 655.) Defendants anticipated that their renovations would be completed by December 2015. If this is true, an injunction will have no negative impact—Defendants will be in full compliance with the Act. However, that does not change the court’s suspicions: Defendants’ past unreliability cause this factor to weigh in favor of granting the government’s motion.

The court, therefore, finds that absent an injunction, there is a substantial likelihood that Defendant will violate the Act in the future.

C. Equitable Factors

Defendants request that the court refrain from issuing the injunction sought for a number of additional reasons. First, Defendants ask the court to “appropriately take notice of the economic problems facing the City of Detroit,” noting that “Detroit definitely needs all the jobs it can retain.” (Dkt. # 26, Pg. ID 654.) “Although the jobs available at Scotty’s are small compared to the total employment available in the City, they still have importance to the City’s economic needs, given the ongoing financial crisis.” (*Id.* at Pg. ID 655.) Be that as it may, Congress has already balanced the policy considerations here and determined that ensuring the public health is worth whatever negative impact enforcement of the statute might have on local economies. The Act contains no

exception for a business laboring in a struggling economy or a city with a particularly high unemployment rate, but places a premium on public health concerns. As such, Defendants' argument is inconsequential.

Second, Defendants argue that an injunction would be inappropriate because there is no "immediate and dire threat to the public health." (*Id.* at Pg. ID 656.) However, the Act requires only that the government show that Defendants have violated the Act in the past and that there is cognizable danger of future violations. See *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). Having found that Defendants have not raised a genuine issue of material fact with respect to either factor, the court will grant the government's Motion for Summary Judgment (Dkt. # 22) and issue an injunction.

IV. CONCLUSION

IT IS SO ORDERED that the government's Motion for Summary Judgment (Dkt. # 22) is GRANTED.

IT IS FURTHER ORDERED that the government shall SUBMIT to the court the form of injunction it believes appropriate no later than **April 1, 2016**. Defendants shall then RESPOND by no later than **April 8, 2016**. The court will hold a telephone conference with counsel on **April 15, 2016 at 9:30 a.m.** If the language of the injunction is not resolved at the conference, the court will hold a formal hearing with party representatives on the matter on **April 26 , 2016 at 9:00 a.m.**

s/Robert H. Cleland
ROBERT H. CLELAND
UNITED STATES DISTRICT JUDGE

Dated: March 28, 2016

I hereby certify that a copy of the foregoing document was mailed to counsel of record on this date, March 28, 2016, by electronic and/or ordinary mail.

s/Lisa Wagner
Case Manager and Deputy Clerk
(313) 234-5522